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: FROM: GARY P. OAKESON

TRANSMITTED BY: BRENDA WISEMAN

OUR DOCKET No.: 01845-22396

FOR: A METHOD FOR REVERSING ALZHEIMER DEMENTIA

SUBJECT: AMENDMENT/RESPONSE

Commissioner For Patents PO Box 1450 Alexandria, VA 22313-1450

Dear Sir/Madam:

Attached please find an Amendment/Response for Docket No. 01845-22396, Application No. 10/750,376.

Thank you. We await your confirmation of receipt.

Respectfully submitted,

ary P. Oakeson

THORPE NORTH & WESTERN, LLP

Customer No. 20,551 Reg. No. 44266

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(Application Number		10/750,376		
TRANSMITTAL	Filing Date	12/31/20	12/31/2003		
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	Art Unit	1616			
(to be used for all correspondence after initial filing)	Examiner Name	Frank I.	Frank I. Choi		
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Application No.: 10/750,376 Docket No.: 01845-22396

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

ART UNIT: 1616 EXAMINER: Frank Choi CERTIFICATE OF MAILING **UNDER 37 C.F.R. § 1.8** FIRST NAMED DATE OF DEPOSIT: June 9, 2008 INVENTOR: Keith A. Rindlesbach I hereby certify that this paper or fee (along SERIAL NO.: 10/750,376 with any paper or fee referred to as being attached or enclosed) is being submitted on the date indicated above via: FILED: 12/31/2003 EFS Web facsimile to 571-273-8300 CONE NO.: 4892 the United States Postal Service with sufficient postage as first class mail

FOR:

A METHOD FOR REVERSING

ALZHEIMER DEMENTIA

DOCKET'NO.: 01845-22396

THORPE NORTH & WESTERN, LLP Customer No. 20,551 P.O. Box 1219 Sandy, Utah 84091-1219

addressed to: Mail Stop

Alexandria, VA 22313-1450.

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Commissioner for Patents, P.O. Box 1450,

AMENDMENT / RESPONSE

. Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action, mailed May 5, 2008, Applicant offers the following , remarks and requests reconsideration of the above-captioned application. This communication is being submitted prior to the expiration of the one month response deadline.

HECEIVED CENTRAL FAX CENTER Application No.: 10/750,376

Docket No.: 01845-22396

JUN 09 2008

BACKGROUND

- 1. The present application was filed on December 31, 2003 under the title A METHOD FOR REVERSING ALZHEIMER DEMENTIA. Twenty claims were presented.
- 2. In the first Office Action mailed July 5, 2006, the Examiner rejected claims 1-20 under U.S.C. § 112, first paragraph for various reasons. Specifically, the Examiner stated that although information as to doses was contained within the specification, the working examples appeared to be prophetic in nature. Additionally, the Examiner stated that the claims were too broad in that they claimed a method where dosing could occur up to 18 hours after dosing one of the ingredients. The Examiner argued that such claims would require one of ordinary skill in the art to do undue experimentation to determine what doses, dosing intervals, order of dosing, etc. would be offective.
- 3. Applicant submitted a response to the Patent Office on November 6, 2006 pointing out that the Examiner assumed that the examples were prophetic without any indication of such from the Applicant, and that nothing in the examples stated or implied that the examples were prophetic. In addition, Applicant explained that the examples have sufficient detail to provide what the Applicant considered to be the invention, and that the examples provide a sufficient dosing regimen to enable it to be followed without undue experimentation. Applicant also comphasized that a person could follow the regimen exactly if they chose to.
- 4. A second Office Action was made final and mailed on January 26, 2007. In that Action, the Examiner maintained the U.S.C. § 112, first paragraph, rejection for claims 1-20. Specifically, the Examiner set forth the same arguments and added that the specification provided insufficient evidence that the combination would be effective in reducing Alzheimer's dementia. In response to Applicant's arguments, the Examiner argued that Applicant provided no evidence refuting the conclusion that the examples were prophetic in nature. The Examiner reasoned that Applicant stated what may occur or what was intended to occur and not that treatment was administered to a patient with a resulting reduction in Alzheimer's dementia. The Examiner reasoned that the enablement requirement was not satisfied although treatment methods were disclosed in the specification.

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- 5. In an effort to expedite prosecution, a telephone interview was conducted involving the Examiner and Counsel for the Applicant. In the interview, the Examiner indicated that the scope of the claims should be more narrowly tailored to the treatments set forth in the examples and indicated that a declaration would be required to address the "prophetic" nature of the examples. The Examiner suggested that the declaration indicate that the examples were not prophetic in nature, and include additional information as to the actual effects observed in the freatment of the Alzheimer's patient. During the conversation it was also agreed that if the amendments and declaration did not put the claims in condition for allowance, the amendments would be entered, the finality of the office action removed, and a telephone interview would be initiated by the Examiner.
- 6. Accordingly, Applicants submitted a response to the second Office Action on March 26, 2007. In the response, Applicants amended claim 1, as suggested by the Examiner, by incorporating dependent claims 2-10 and 16 to reflect the treatment outlined in example 1 of the application. Accordingly, claims 2-10 and 16 were cancelled. This was an amendment that the Applicant did not think was warranted by current U.S. patent law, but did so for economy purposes to put the case in condition for allowance. In addition, as per the Examiner's suggestion, Applicants submitted a declaration indicating that the examples were not prophetic in nature (which the Applicant also does not believe was necessary), and that a patient treated in accordance with the example had experienced a decrease in Alzheimer's dementia through treatment according to the practice of example 1 of the specification. The declaration further included information as to the effects observed in the patient as the patient was treated in accordance with the combination and method disclosed in the application.
- 7. In response to Applicant's response of March 26, 2007, the Examiner submitted an Advisory Action on July 19, 2007. In the Advisory Action, the Examiner failed to enter the amendments or declaration as agreed upon in the telephone interview, and indicated that the request for reconsideration did not place the application in a condition for allowance since the amendments and declaration had not been entered. The Examiner accordingly rejected the claims for the reasons set forth in the Final Office Action. The Advisory Action indicated that the amendments were not entered because the Examiner felt they raised new issues that would require further consideration and/or a search; and they were not deemed to place the application

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in better form for appeal by materially reducing or simplifying the issues for appeal.

- 8. The Advisory Action further indicated that the declaration was not entered because the Examiner felt the Applicant had failed to provide a showing of good and sufficient reasons why the declaration was necessary and was not earlier presented. The Advisory Action also indicated that the declaration was not entered because it would require further consideration and/or a search due to the fact that the declaration indicated that the examples were not hypothetical, but provided no data or records to support that conclusion. It should further be noted that the Examiner did not make an attempt to initiate a telephone interview with Applicant's Counsel as was previously agreed upon.
- 9. After receiving the Advisory Action on the present application, particularly where the Examiner failed to enter the amendments and declaration after suggesting that they be submitted, Applicants decided it would be beneficial to appeal the present claims. Accordingly, Applicants filed a Notice of Appeal on July 19, 2007, followed by an Appeal Brief dated August 17, 2007.
- 10. In response to Applicant's Appeal Brief, the Examiner reopened prosecution, issued an Office Action dated November 5, 2007, and entered Applicant's amendment, which the Examiner had previously refused to enter. In this Office Action, the Examining Attorney issued a new rejection with respect to the amended claims under 35 USC §112. In that Office Action, the Examiner indicated that Applicant could respond to the Office Action by filing a new appeal brief under 37 CFR 41.37.
- 11. Per the November 5, 2007 Office Action, Applicant responded by filing a new appeal brief dated February 26, 2008. In the appeal brief, Applicant amended the claims back to the original claims in the application (the same claims that existed at the time of the original appeal brief).
- 12. The Examiner responded to Applicant's Appeal Brief on in Office Action dated May 7, 2008 (the most recent Office Action). In this Office Action, the Examiner dismissed the Appeal and indicated that the Appeal Brief would be treated as a reply to the Office Action, and more particularly be treated as a non-responsive amendment.

In the most recent Office Action, the Examining Attorney indicates that "the enablement rejection cannot be considered most on the basis that Applicant's amendment purportedly reinstates the subject matter of the original claims." See 5-7-08 Office Action, page 3.

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Specifically, the Examining Attorney argues that Applicant has not shown how the subject matter of the original claims overcomes the enablement rejection as set forth in the Office Action dated November 5, 2007. The Examiner further argues that Applicant does not address the Normann et al. references which are cited in the November 5, 2007 Office Action as evidence supporting non-enablement.